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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,363	02/29/2000	Paul B. Fisher	A34614/070050.1690	1657

7590 04/07/2006

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/515,363	Applicant(s) FISHER ET AL.	
	Examiner Celine X. Qian Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 2 is/are allowed.
- 6) ☒ Claim(s) 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0206</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11 are pending in the application.

This Office action is in response to the Amendment filed on 2/6/06.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/6/06 has been entered.

Response to Amendment

The rejection of claims 4-11 under 35 U.S.C. 112 1st paragraph is maintained for reasons set forth of the record mailed on 10/31/05 and further discussed below.

Response to Arguments

In response to the new matter rejection, Applicants argue that citing the specification at page 52 and 57 was to support an additional limitation introduced to claim 4, wherein such limitation more clearly set forth the nature of the homology relationship and to require that the encompassed molecule to encode proteins which comprise a caspase recruitment domain and an RNA helicase domain. Applicants further assert that support for nucleic acids having 90% homology to SEQ ID NO:1 has been cited in the previous response. Applicants thus conclude that the amendment does not contain new matter. Applicants allege that the examiner has merely reiterated a rejection that is fully addressed in prior responses. Applicants thus conclude that the instant specification supports the newly introduced limitations.

This argument has been fully considered but deemed unpersuasive. As discussed in the previous office action, there is no support in the specification for the claimed nucleic acid(s) because the passages cited by Applicants (page 52, lines 6-8, and page 57, lines 21-25) are directed to Mda-5 polynucleotide and polypeptide only. The specification teaches that Mda-5 is encoded by cDNA as disclosed in SEQ ID NO:1, not nucleic acid having 90% homology of SEQ ID NO:1. The MPEP states: "While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." The fact one working example in the specification on page 52 and 57 discloses the protein encoded by the nucleic acid molecule SEQ ID NO:1 comprises "a caspase recruitment domain and a RNA helicase domain, and introduction of the isolated nucleic acid molecule into a HO-1 melanoma cell leading to expression of the encoded protein reduces the cell's colony forming ability", that applicant may now wish to have other polypeptide encoded by sequences 90% homologous to SEQ ID NO:1 broadly covered by the scope of the new claims after the filing date of the as-filed application, does not provide any legal basis showing that applicant possesses the specific claimed subject matter as claimed in the new claims at the time the invention was made. Thus, this is a new matter rejection. In other words, new or amended claims which introduce elements or limitations such as a subgenus of nucleic acids having the recited function, which covers nucleic acids comprising 92% homology with SEQ ID NO:1, and which are not supported by the as-filed disclosure as a whole, violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not

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necessarily described by a genus encompassing it and a species upon which it reads). Contrary to Applicant's assertion, this rejection is necessitated by Applicant's amendment filed on 8/12/05, which cannot be possibly addressed by prior filed responses. For reasons set forth of the record and discussed above, this rejection is maintained.

Conclusion

Claims 1 and 2 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'C. Qian', written over a horizontal line.